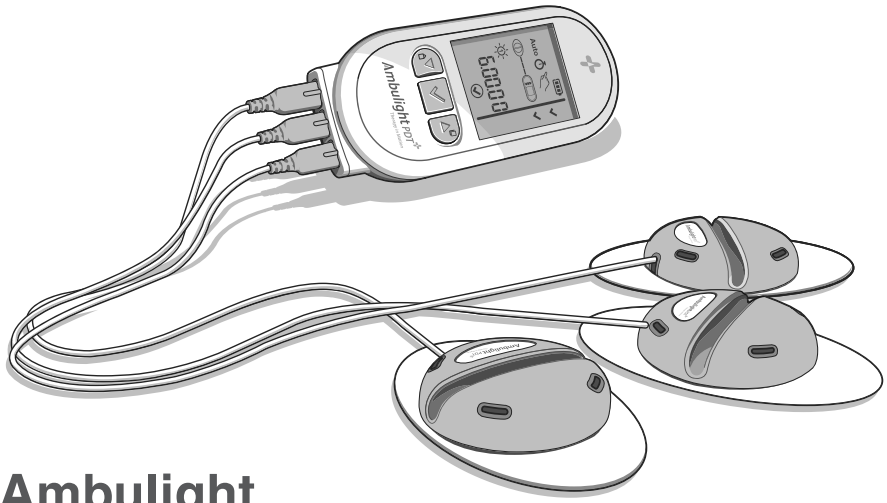
Ambulight PDT

Therapy in Motion



Ambulight PDT Multi / Instructions for Use

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Description of Ambulight PDT Multi

The Ambulight PDT Multi is a light source intended for use in topical Photodynamic Therapy (PDT) of skin lesions.
The Ambulight PDT Multi emits light with a peak wavelength of 640nm, and a Full Width Half Maximum (FWHM) of 20nm.
The irradiance of light emitted from each light emitting treatment head of the Ambulight PDT Multi is 7 mW/cm^2.

The Ambulight PDT Multi consists of two separate sections; a reusable controller and a single use, disposable light emitting treatment head. These are supplied separately. Up to three disposable light emitting treatment head can be connected to any Ambulight PDT Multi controller.

The Ambulight PDT Multi emits a total light dose of 75 J/cm^2

Indication of Use

The Ambulight PDT Multi device is intended to locally deliver the light required for a topical Photodynamic Therapy (PDT) treatment of non-melanoma skin cancer lesions which are less than 2.4 cm in diameter, superficial basal cell carcinoma, actinic keratosis and Bowen's disease. This device is intended to be used in combination with a photosensitising pharmaceutical indicated for the treatment of non-melanoma skin cancer.

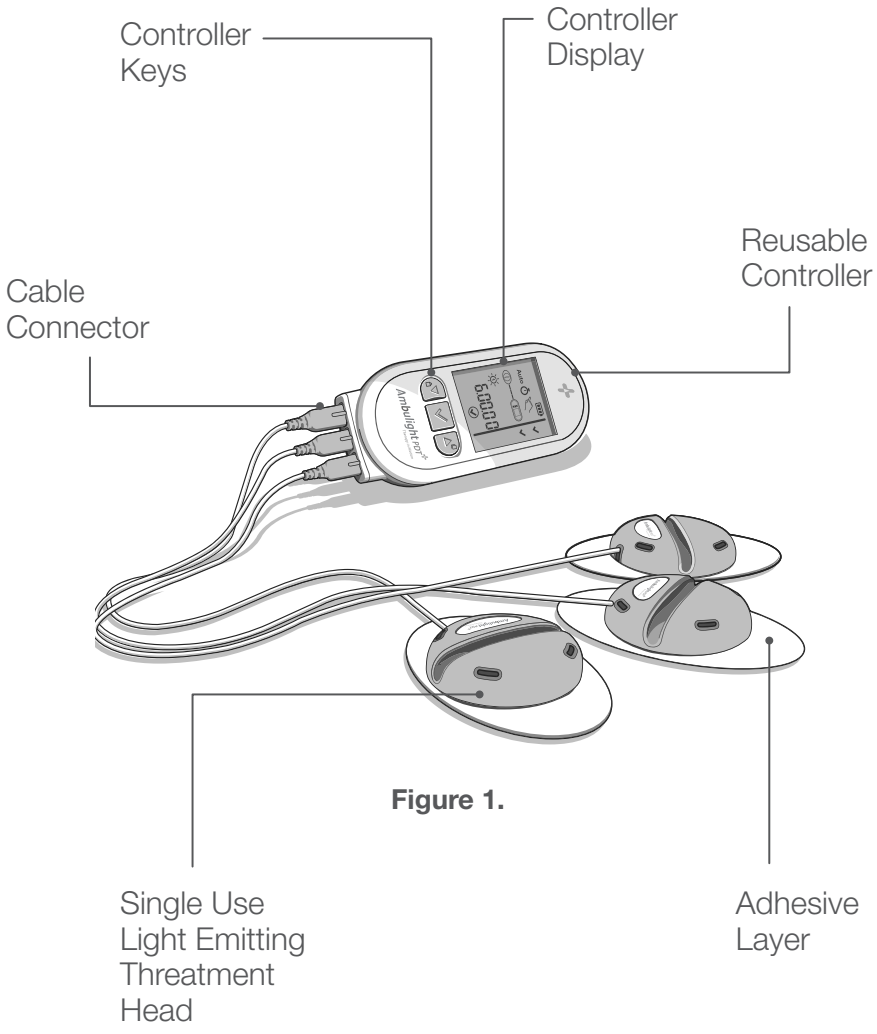

Controller
Keys
Controller
Display
Reusable
Controller
Cable
Connector
Single Use
Light Emitting
Threatment
Head
Adhesive
Layer

Figure 1.

Contraindications

The Ambulight PDT Multi is intended to be used in combination with a pharmaceutical indicated for the treatment of non-melanoma skin cancer. Please refer to the specific product characteristics (SPC) accompanying the pharmaceutical for a list of contraindications.

The Ambulight PDT Multi is intended to be used with a transparent occlusive dressing. Please refer to the information leaflet accompanying the transparent occlusive dressing for a further list of contraindications.

Patients with a history of abnormal photosensitivity should not use the Ambulight PDT Multi.

Warnings and Precautions

The Ambulight PDT Multi is only to be used by a qualified healthcare professional (HCP)

The Ambulight PDT Multi consists of two parts; the control unit and the light emitting treatment head. The light emitting treatment head is a single use device; it should not be re-used nor transferred between patients. The control unit is a reusable device and should be cleaned after each use.

The Ambulight PDT Multi should only be used with lesions with a maximum diameter of 24mm at their widest point. All lesions should fit completely within the central circle of the alignment template, supplied with the disposable light emitting treatment head.

If the light emitting treatment head(s) should become detached from the treatment area do not allow the light source to shine into the eye.

For lesions that are located on curved treatment areas, the light emitting treatment heads should be rotated around the lesion such that the hinge of the device allows it to bend around the treatment area. See Appendix 1 for further details.

Should the HCP foresee a risk that the connection between the light emitting treatment head and the controller may become disconnected during treatment, the connecting cable should be placed beneath the clothing to minimise this risk. If the display on the controller indicates the word ‘ERROR’ during use then please refer to the troubleshooting section in Appendix 2.

The transparent occlusive layer should allow at least 95% of the incident light to pass through the layer. You should ensure that your choice of a transparent occlusive layer that will ensure that this requirement is met.

For a list of anatomical positions where the Ambulight PDT Multi should not be used, please refer to the Treatment Position Restrictions section of this manual.

Only use the Ambulight PDT Multi between the temperatures (10 °C to 40 °C)

WARNING! Modification of equipment may affect treatment outcomes and is not permitted under the Ambulight PDT Multi licence for use.

Important Dual Mode Operation

The Ambulight PDT Multi has two modes; automatic mode and manual mode.

Automatic Mode

If the Ambulight PDT Multi is placed into automatic mode then the device will automatically deliver a total light dose of 75 J/cm^2 to the illuminated treatment site.

The entire treatment time in automatic mode is 6 hours;

3 hours wearing the treatment head with light off to allow for absorption of the photosensitizing pharmaceutical and 3 hours wearing the treatment head with light on to activate the photosensitizing pharmaceutical.

It should be noted that the device, occlusive dressing and pharmaceutical are applied to the patient at the same time and remain in place for the entire 6 hour treatment cycle

Manual Mode

In manual mode the incubation time and illuminated time can be set according to the HCP's treatment protocol.

When illuminated, the Ambulight PDT Multi operates at an irradiance of 7 mW/cm^2. The total dose will therefore be determined by the duration of illumination selected by the HCP.

Contents of Controller Box

The box contains;

1. This instruction booklet (IFU).
2. The Ambulight PDT Multi control unit.
3. A mains charger for charging the control unit.
4. A plastic carry case for returning the Ambulight PDT Multi to the clinic.

Contents of Light Emitting Treatment Head Box

This box contains;

1. A light source for illuminating a pharmaceutical as part of a Photodynamic Therapy treatment.
2. An alignment template for aligning the light source to the treatment area.
3. An instruction booklet.

Treatment Location Restrictions

The following areas should not be treated with Ambulight PDT Multi;

- Facial areas indicated in **Figure 2**, including; the eye socket nose tip and folds and the lips.
- Fingers.
- Toes.
- Ears.
- Genitals.

All other external surfaces of the body can be treated with the Ambulight PDT Multi.

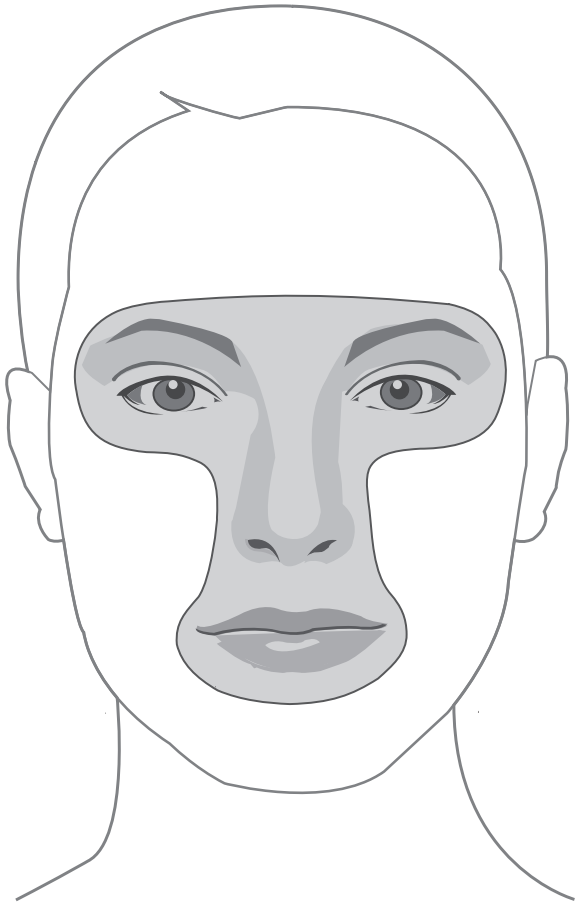


Figure 2.
Illustration of the areas of the face that should not be treated with the Ambulight PDT Multi. Areas shaded in gray should not be treated.

Charging

The Ambulight PDT Multi is a portable medical device that relies on a battery to effectively deliver sufficient power for a therapeutic treatment. Unlike portable devices such as mobile phones, the Ambulight PDT Multi must be fully charged before the treatment starts. This is critical to ensure that the device can complete an entire treatment. To guarantee that the device is able to deliver a full treatment it must learn what the maximum battery charge is. It must therefore undergo an initial battery learning cycle.

Initial Battery Charge Learning Phase

The first time that the Ambulight PDT Multi is used it must undergo an initial learning phase before a therapeutic treatment can take place, this is so that it can determine the maximum battery charge.

The initial charging process is as follows;

1. Connect the control unit to the mains electricity via the supplied charger for **24 hours**.
2. Disconnect the charger from the controller.
3. Re-connect the charger to controller and charge until the battery icon stops being animated.
4. Disconnect the charger and use the device.

Battery Charging Process

In order to undergo the initial learning phase the device should be plugged into the charger and charged for 24 hours. At the end of this time the unit will have learnt what the maximum battery charge is.

To exit the device from this learning phase simply disconnect the unit from the charger after the 24 hours has elapsed.

Re-connecting the unit to the charger from now on will charge the device in a normal charge mode. The battery icon will be animated to show that the device is charging. Given that the device has had a significant amount of charge during the learning phase this initial re-charge after the learning phase should only take a short amount of time. However this may vary and it is important that the device is charged until the battery indicator displays all 3 bars as being full, this may take up to three hours.

The above learning phase only needs to be done the first time that you receive the Ambulight Multi [however see notes below]. After this you can charge the unit as you would any other electrical product. A full re-charge under normal use typically takes 4-5 hours.

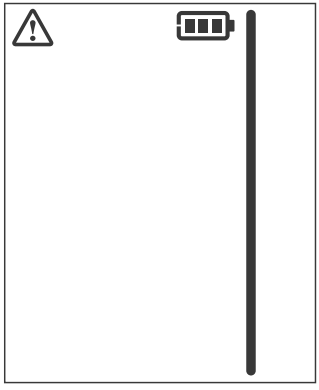
Notes on use

The Ambulight PDT Multi slowly loses its charge even if it is not used. So for example if the device is fully charged on day 1, and the device disconnected from the charger. By day 2 or 3 the controller may have lost sufficient charge on its own that the device may not allow you to start a new treatment even if the device has been switched off during this period. It is therefore recommended that the unit is left charging at all times between use, this ensures that the unit is always ready to go when needed.

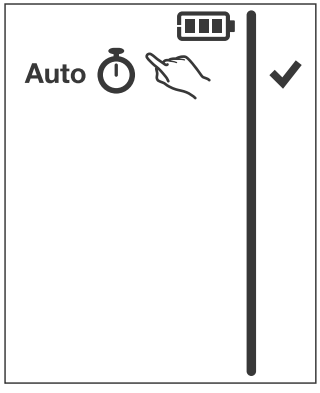
If the unit is left for a long time between charges the battery may become completely flat. If this happens the initial learning phase must be repeated.

Battery Charge Before Use

If the battery is not fully charged before use, and therefore the controller is not capable of delivering a full treatment, then the Ambulight PDT Multi will not allow the user to operate the device and the following screen will be shown on the controller.



Once the battery is fully charged the following screen will be shown and the user will be allowed to operate the Ambulight Multi.



Required Materials

1. Ambulight PDT Multi control unit. Included in the controller box.

2. Ambulight PDT Multi light source (1, 2 or up to 3 light emitting treatment heads may be used simultaneously with one Ambulight PDT Multi Controller) Included in the treatment head box.

3. Alignment template (see **Figure 3.**). Included in the treatment head box.

4. Transparent occlusive dressing at least 3cm x 3cm in diameter. Sourced separately.

5. Photosensitising pharmaceutical. Sourced separately.

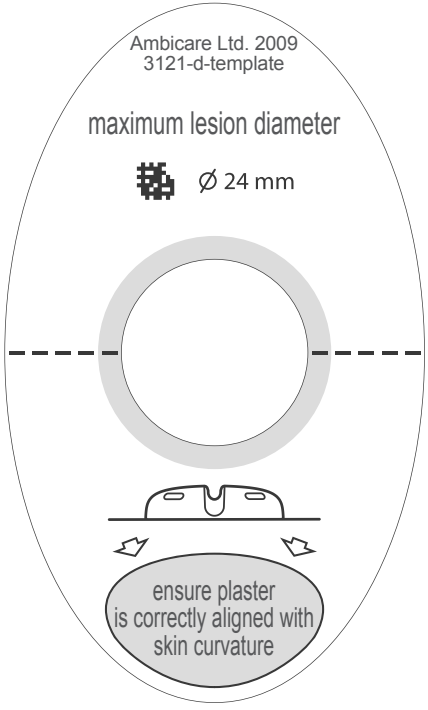


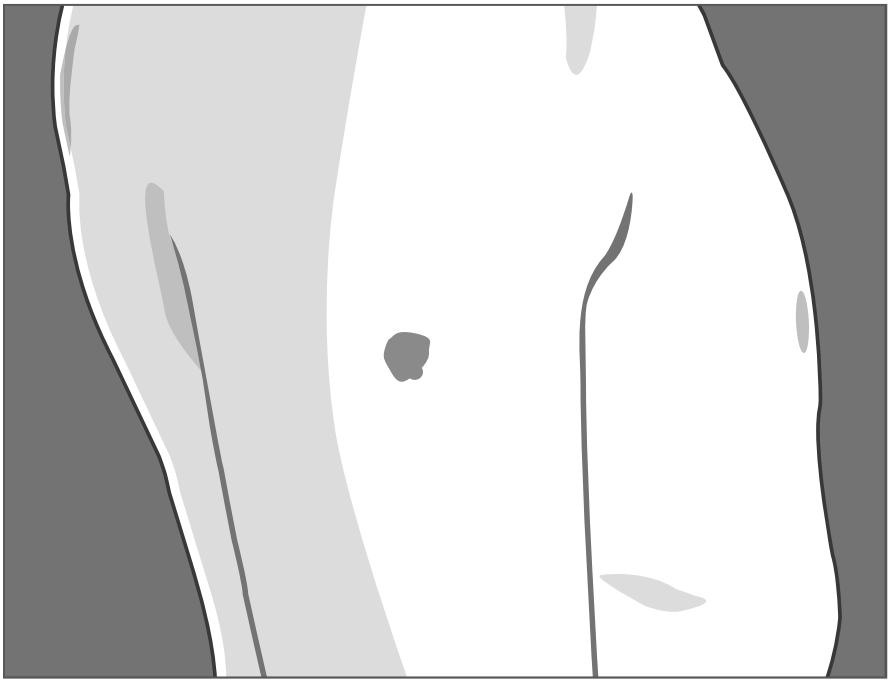
Figure 3.

Attaching the Light Emitting Treatment head to the Treatment Site

1. Before preparing the lesion, the position and orientation of the light source on the skin should be determined.

2. The location of the lesion should be checked against the permitted locations as described in this booklet.

3. Areas that are covered with hair should be shaved prior to the pharmaceutical application.

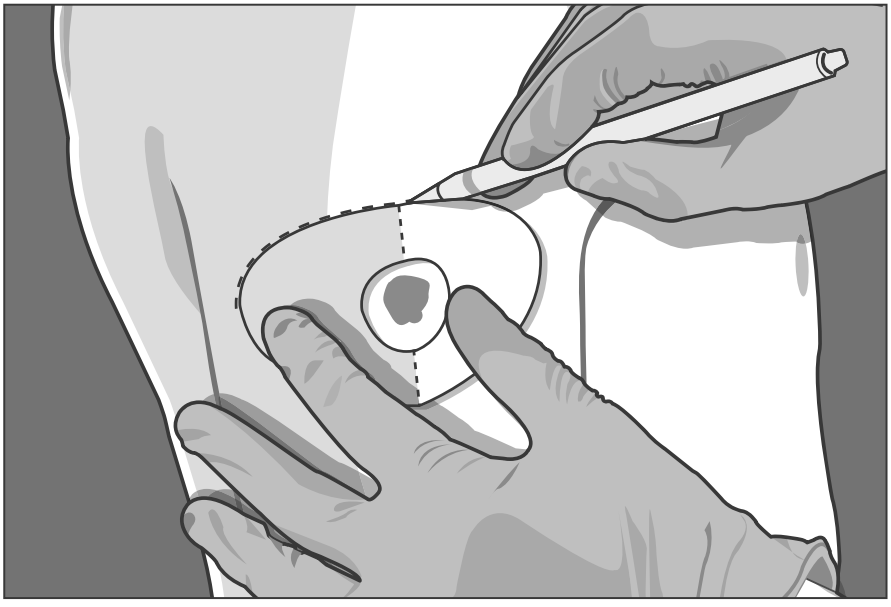


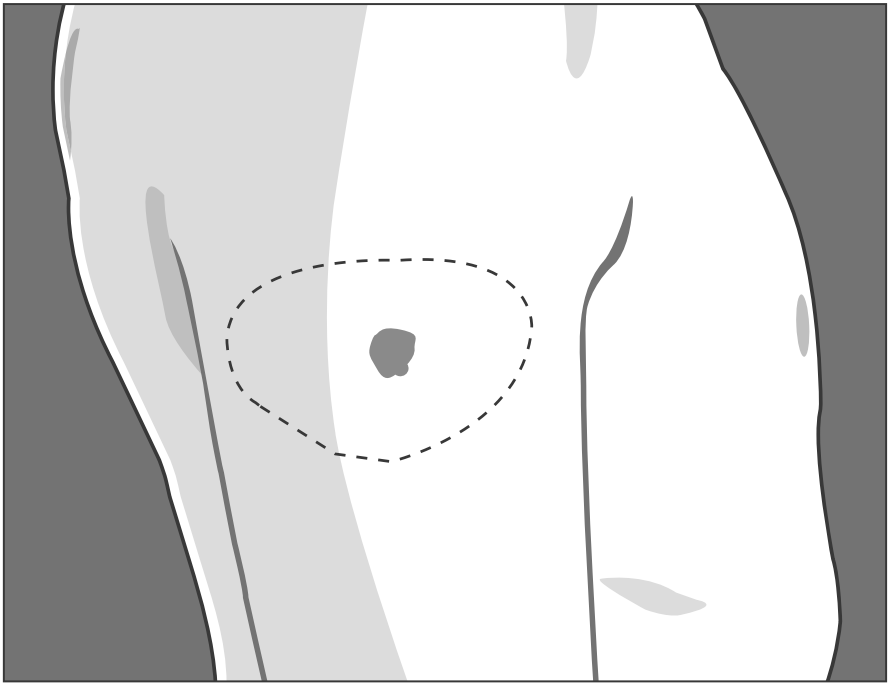
4. The alignment template (and not the transparent occlusive dressing) should be placed on the skin over the lesion and aligned such that the lesion sits in the middle of the circle on the template.

5. The lesion should be no greater than 24mm in diameter at its widest point and fit completely within the circle of the template.

6. For lesions that are located on curved body surfaces, the template should be rotated around the lesion such that the hinge of the device allows it to bend around the body curve. *See Appendix 1 for further details*

7. Dots or lines should be made on the skin using a skin marker to illustrate the location of the template over the lesion.

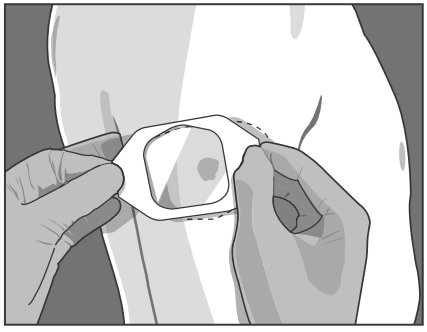


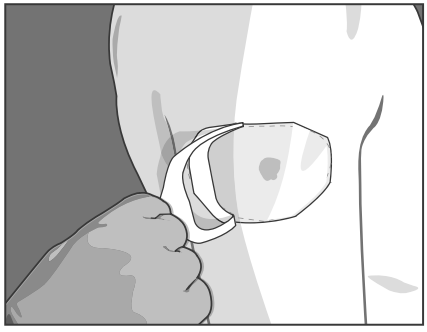


8. Before applying the pharmaceutical, the lesion surface should be prepared to remove scales and crusts and roughen the surface of the lesions. Please refer to the pharmaceutical instructions for a protocol of how this should be achieved.

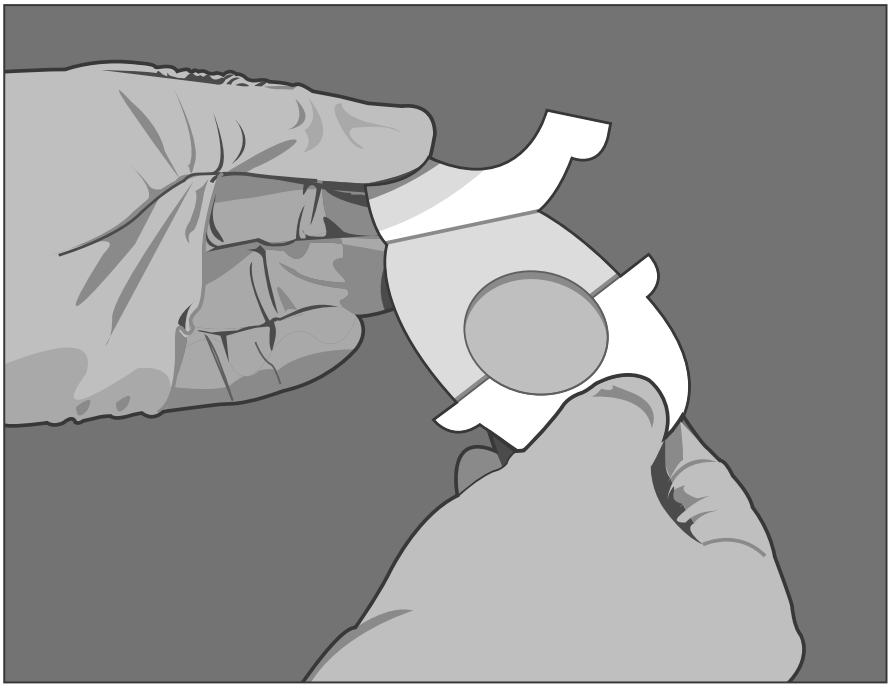
9. The pharmaceutical should be applied in an even 1mm thick layer across the extent of the lesion. This ensures that the pharmaceutical will be absorbed into the skin and therefore becomes transparent before the light source is activated. The pharmaceutical covering should extend past the lesion margins by a distance of 5-10mm.

10. When the pharmaceutical has been applied as described above the entire area should be covered with a transparent occlusive dressing. This dressing should have dimensions of at least 3 cm x 3 cm. Slight pressure should then be applied to the area to ensure that a 1mm thick continuous layer of pharmaceutical covers the lesion and extends beyond the lesion margin to a distance of 5mm.



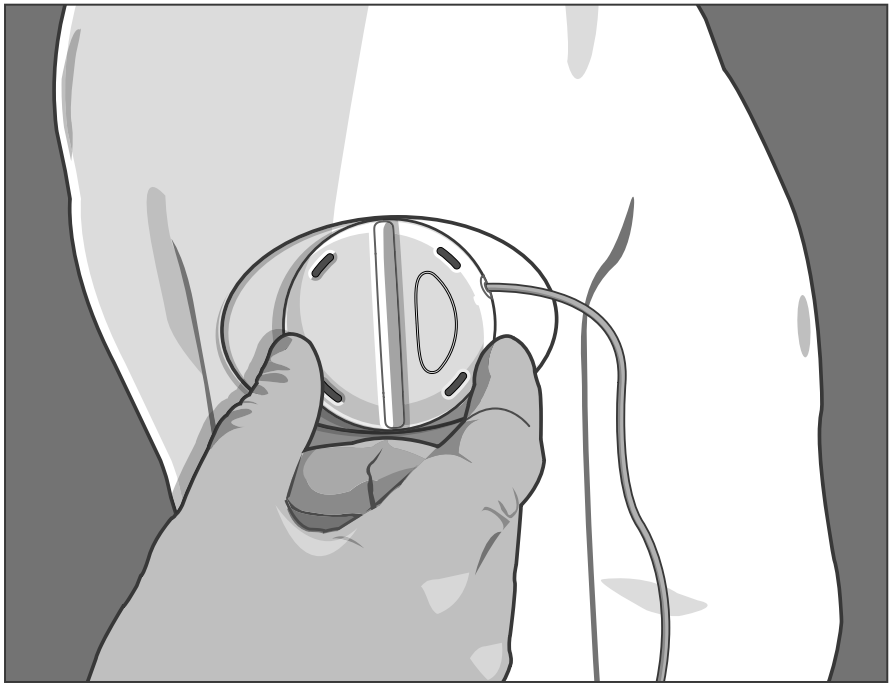


11. The adhesive liner on the light emitting treatment head should be unpeeled to expose the adhesive.



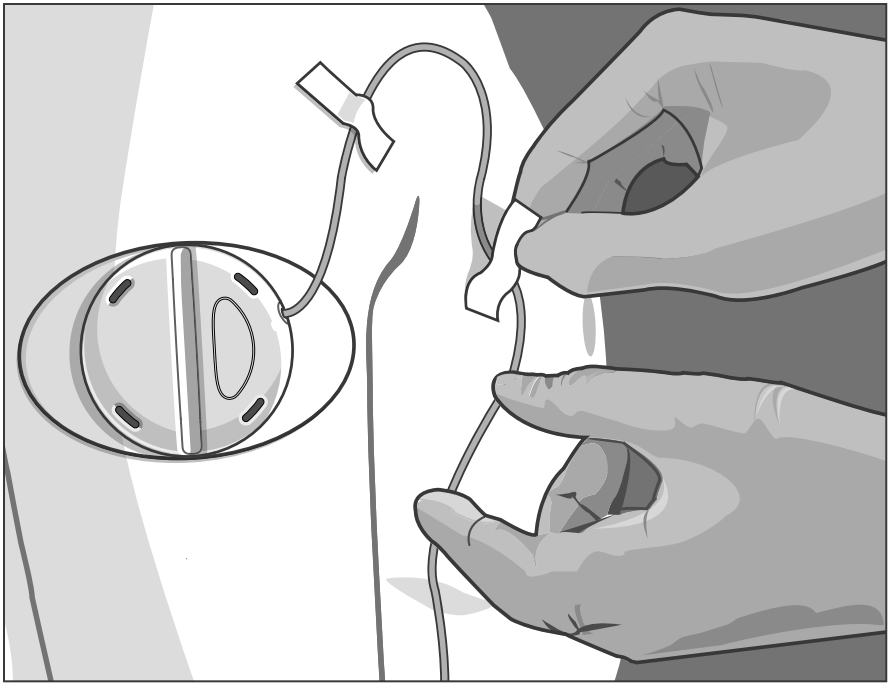
12. The light emitting treatment head should then be placed over the lesion and occlusive dressing layer such that it aligns with the marks that were made with the alignment template.

See Appendix 1 for additional information on alignment of the treatment head.



13. Instances where the power cord may get snagged during use require that the path of the power cord from the battery pack to the light source go under the clothes of the patient. The power cord should be attached to the patient at distances of 25cm using adhesive strips.

The adhesive strips should be placed in such a manner that the cord has enough slack to ensure it does not impede the normal movement of the patient.



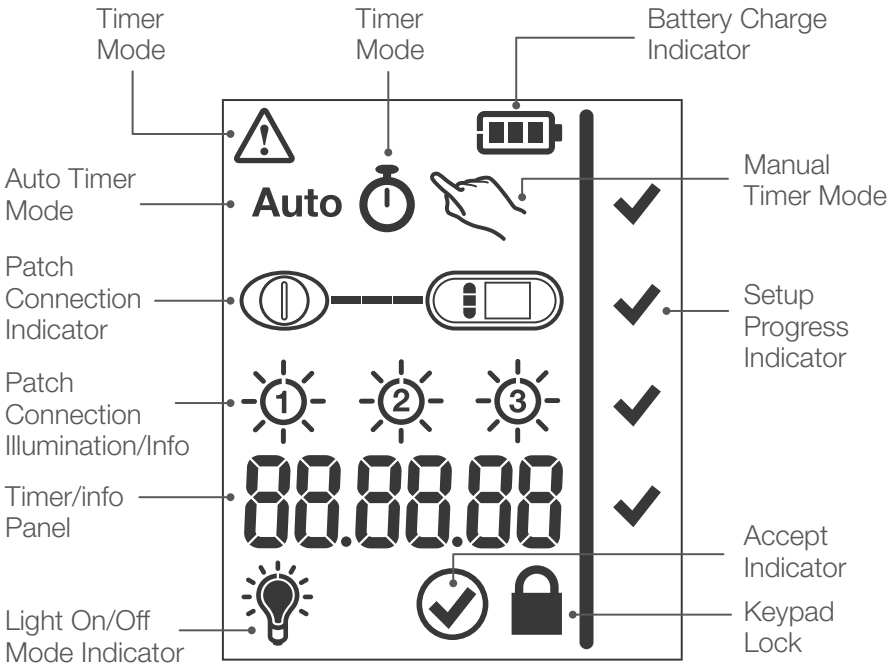
Notes on use

- Healthy skin surrounding the lesion does not need to be protected during illumination.

- Up to three lesions may be connected to an Ambulight PDT Multi controller and treated at the same time.

Operation of the Control Unit

Screen 1 shows the main features of the control unit display.



Screen 1.

Ambulight PDT Multi Keys

The Ambulight PDT Multi has the following keys:

Down Key (Key 1)
Use to decrease a number.

Select Key (Key 2)
Use to select or accept a function, and to turn the unit.

Up Key (Key 3)
Use to increase a number.

First Time Setup

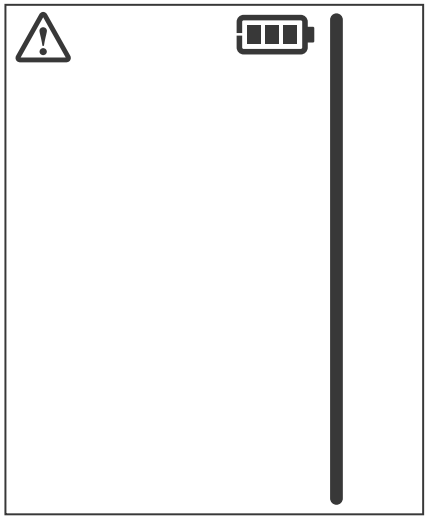
Before first use the controller unit must be charged for a minimum of 24 hours.

Turning the Ambulight PDT Multi on/off

To turn the Ambulight PDT Multi on press and hold the Select Key for 2 seconds.

The controller will check the state of the battery to ensure that there is enough charge for a full treatment of three hours illumination.

If there isn't enough battery power then **Screen 2** will be shown. **Please connect the controller to the charger to completely charge the battery. Please refer to the section 'Charging' in this IFU for further details on handling of the battery**



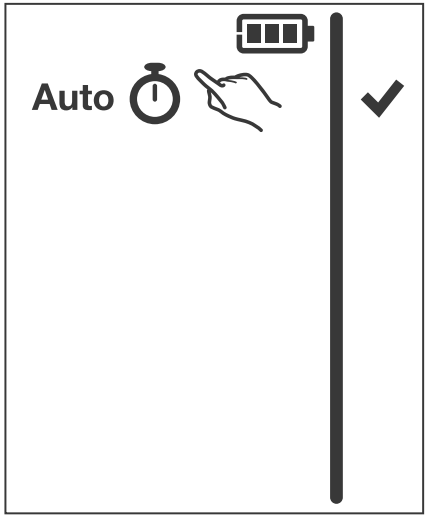
Screen 2.

If the battery is full, then **Screen 3** will be shown.

On this screen the Auto symbol and the tick symbol will be flashing. By pressing the up/down keys you will toggle between the auto symbol and the hand symbol.

The Auto symbol corresponds to Automatic Mode and the hand symbol corresponds to Manual Mode.

Auto = Automatic Mode
Hand = Manual Mode



Screen 3.

Operating the Ambulight PDT Multi – *Automatic Mode*

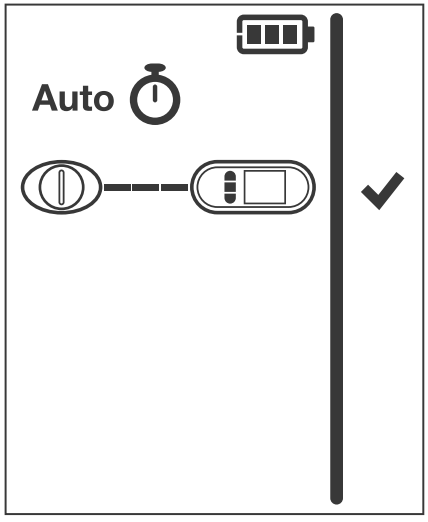
If you wish to operate the Ambulight PDT Multi in Automatic mode, press the up/down keys to ensure that the Auto symbol is on the screen.

Then press the **Select Key.**

Screen 4 will be shown...

The line between the light emitting treatment head and controller will be animated to show that the light emitting treatment head(s) should now be connected to the controller.

Any light emitting treatment head(s) that have already been correctly placed over the lesions to be treated should now be connected to the Ambulight PDT Multi controller.

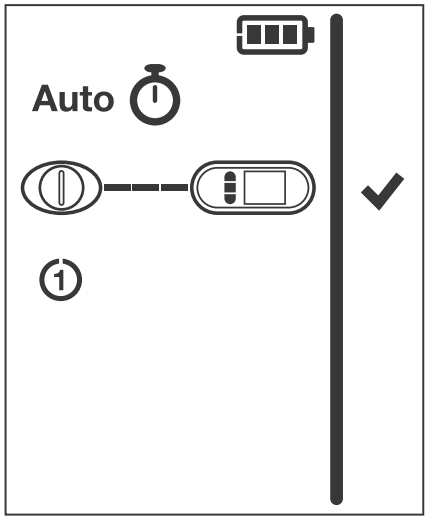


Screen 4.

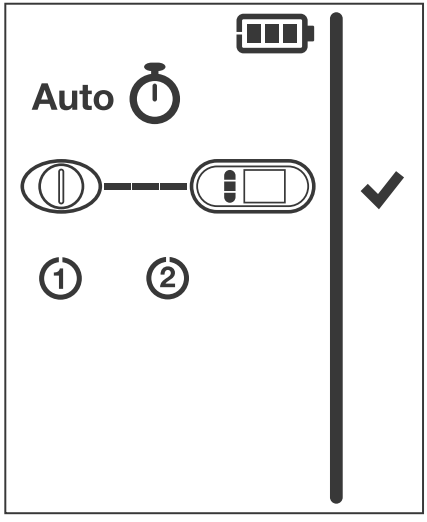
As light emitting treatment heads are connected to the controller they will appear as numbered circles on the display. In **Screen 5a** one light emitting treatment head has been connected to the controller.

Other numbered circles will appear on the screen as the other light emitting treatment heads are connected to the controller. **(See Screen 5b)**

Once the desired number of light emitting treatment heads has been connected to the controller press the **Select Key.**



Screen 5a.



Screen 5b.

Screen 6 will appear and the bottom tick will be flashing (in this instance one light emitting treatment head has been attached).

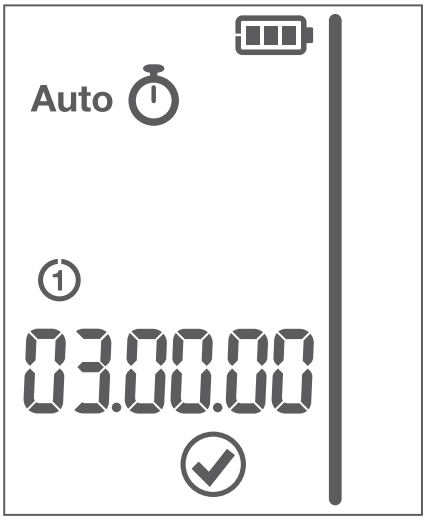
If the correct number of light emitting treatment heads have been applied to the treatment area, and have also been registered on the screen, the treatment can be activated.

To start the treatment, the Select Key should be pressed.

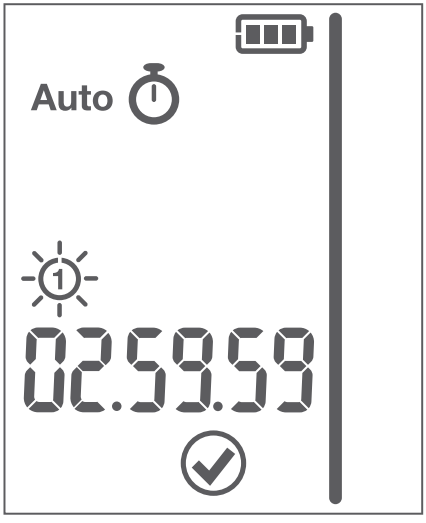
The timer/info panel will appear **(see Screen 7)** and the treatment will activate.

If the treatment is proceeding correctly, the light rays surrounding each light emitting treatment head will flash simultaneously.

The time remaining to the end of the treatment will also be shown on the screen.



Screen 6.



Screen 7.

Notes on Treatment in Automatic Mode

In Automatic mode, the Ambulight PDT Multi is programmed so that the light source does not illuminate until three hours after the treatment cycle has initiated.

After the initial three hours of the treatment cycle, the light source will automatically activate and illuminate the lesion(s) for 3 hours

The device will supply light with a wavelength of 640 nm and will deliver a dose of 75 J/cm^2 to each lesion.

The device will illuminate the lesion(s) for a period of three hours and will ensure that the correct dose has been administered.

The entire treatment cycle time is 6 hours;

3 hours wearing the treatment head without illumination to allow the photosensitising pharmaceutical to be absorbed and 3 hours wearing the treatment head with the light illuminated to activate the photosensitising pharmaceutical.

The treatment can be interrupted any time in the first 60 seconds of treatment by holding down the select key for 10 seconds.

If an error is made during set hold down the up key for 5 seconds to go back to the previous step in the setup process.

Healthy skin surrounding the lesion does not need to be protected during illumination.

Up to three lesions may be connected to an Ambulight PDT Multi controller and treated at the same time.

Operating the Ambulight PDT Multi – *Manual Mode*

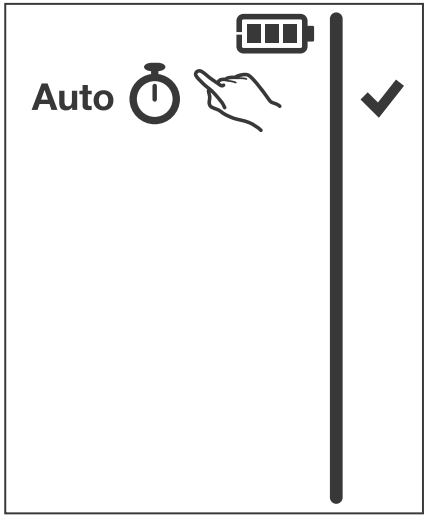
If a time schedule other than that specified in Auto mode (i.e. 3 hours incubation time then 3 hours illumination time) is required a custom time schedule can be programmed into the Ambulight PDT Multi controller using Manual mode.

Please note that the illumination schedule for the pharmaceutical should always be followed.

By pressing the up/down keys the display can be toggled between the Auto symbol and the hand. **(See Screen 3)**

The Auto symbol corresponds to Automatic Mode and the hand symbol corresponds to Manual Mode

Auto = Automatic Mode
Hand = Manual Mode

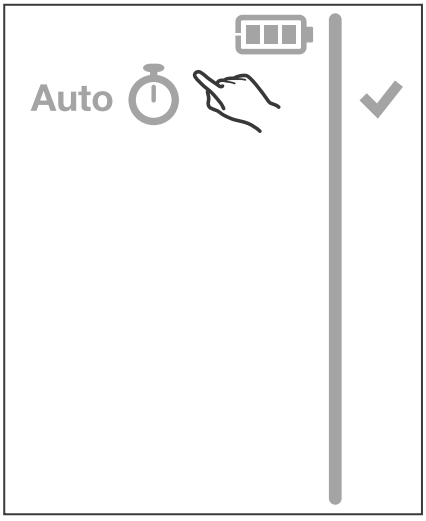


Screen 3.

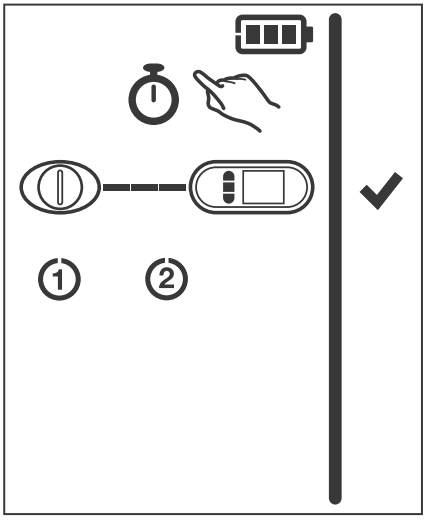
To enter Manual mode, the user should ensure that the hand symbol is visible and flashing on the screen, then press the **Select Key.**

As with the automatic mode the light emitting treatment head(s) should be connected to the controller, they will appear on the controller display as they are attached. **Screen 9** shows the screen once two light emitting treatment heads have been connected.

When the correct number of light emitting treatment heads are connected, the **Select Key** should be pressed.



Screen 8.



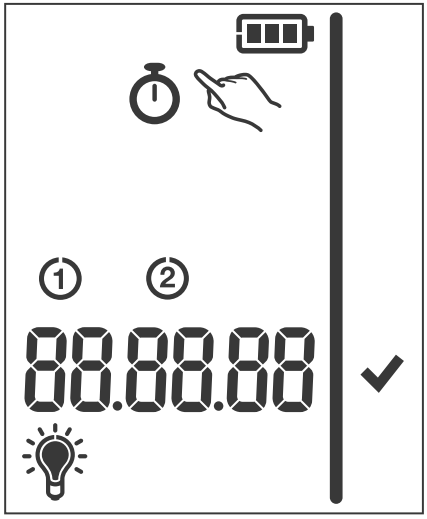
Screen 9.

The controller will now enter manual mode. In manual mode **Screen 10a** will be displayed which contains a darkened light bulb, which represents the photosensitising pharmaceutical incubation time when the light emitting treatment heads will not illuminate.

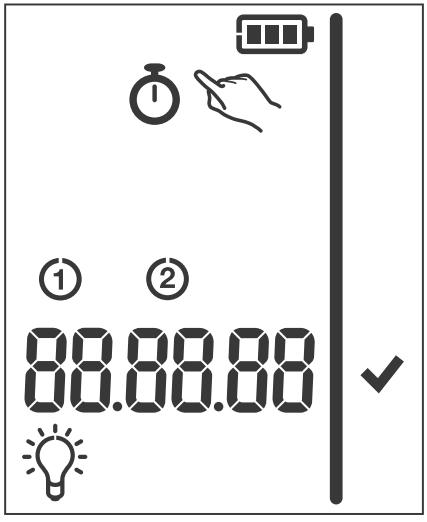
Above this light bulb is the timer. By pressing the up and down keys you can select an incubation time on the screen. The time can be increased in increments of 5 mins.

When the desired initial incubation time has been chosen press the **Select Key.**

The light bulb will then change colour to indicate the illumination time. **See Screen 10b.** When the light bulb is in illumination mode the timer can be set again, thereby representing the illumination time of the treatment cycle.



Screen 10a.

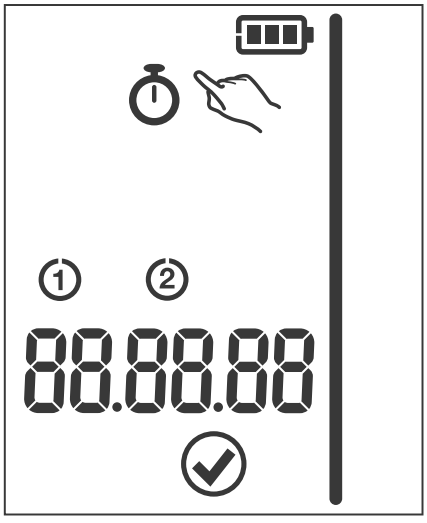


Screen 10b.

When you have selected both the incubation time and illumination time, you should press the **Select Key.**

Screen 11 will be displayed.

By pressing the **Select Key** again, the treatment will start and proceed with the chosen treatment cycle.



Screen 11.

Treatment Protocol – *Patient Involvement*

When the treatment has commenced, the Ambulight PDT Multi will perform all of the timings that are required to complete the treatment. There should therefore be no need for further interaction until the end of the treatment when the device should be removed.

The device is entirely ambulatory. The HCP should assess the patient's competence and govern the extent of supervision required during the treatment cycle.

Similarly the HCP should assess the patient's competence to remove the device and dressings following treatment and their ability to clean and dress the treatment area.

When the Ambulight PDT Multi is removed, the treatment area should be treated according to the pharmaceutical instructions.

When removed the device should be placed in the carry case. The controller should be placed on the side for the controller, and the light emitting treatment heads should be placed alongside the controller in the carry case.

Cleaning and Maintenance

The controller and carry case are reusable and should be hygienically cleaned for multiple patients.

Caution: Do not immerse the device in liquid or allow any liquid to enter the enclosure or any opening.

Warning: The device is not water resistant. Take care to protect the device from coming in contact with liquids.

The device should be cleaned after each usage.

Cleaning is the process of removing organic matter such as dust, soil and other foreign material.

Prior to cleaning ensure all cables are removed.

To clean the exterior of the device, use a soft cloth lightly dampened with Isopropyl Alcohol or 70% alcohol hard surface wipes e.g. Azowipes, Cliniwipes, Tuffi wipes.

Allow to air dry prior to storage.

Caution: When required always clean and disinfect in accordance with current hospital protocols.

Notes on use

The treatment can be interrupted any time in the first 60 seconds of treatment by holding down the select key for 10 seconds.

If an error is made during set uphold down the up key for 5 seconds to go back to the previous step in the setup process.

Healthy skin surrounding the lesion does not need to be protected during illumination.

Up to three lesions may be connected to an Ambulight PDT Multi controller and treated at the same time.

The treatment can be stopped in the middle of the treatment by holding down both the up and down keys for 30 seconds.

Disposal of the Device

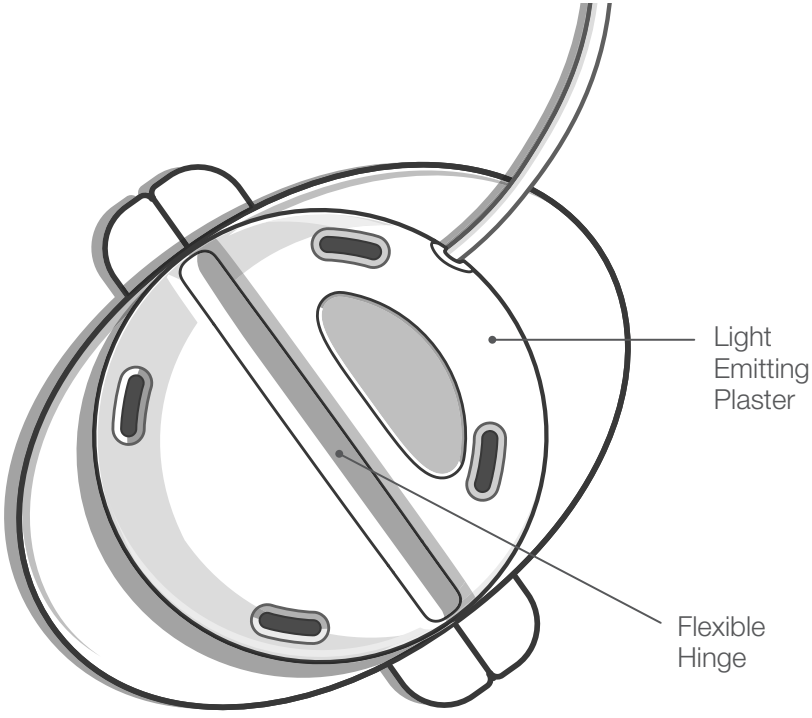
The above symbol denotes that the Ambulight PDT Multi should not be disposed of as general household waste in Europe.

To ensure the correct waste treatment of the product, please dispose of it in accordance with any local requirements for disposal of electrical equipment.

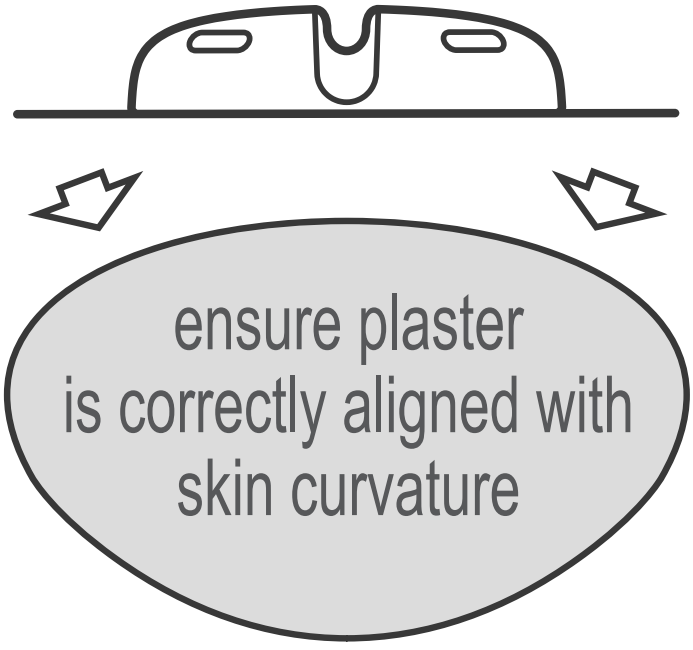
Appendix 1

Alignment of Device on Curved Surfaces

The light emitting treatment head is designed to flex along its central hinge. This thereby allows the device to conform to curved treatment sites.



The light emitting treatment head should be aligned such that the hinge allows the plaster to conform around the curved surface.



Appendix 2 - *Troubleshooting*

If the treatment head becomes detached from the patient during use

If the treatment head should become detached from the patient before the treatment cycle is complete the following protocol should be followed:

1. Note the time at which the treatment head became detached from the patient.
2. Return the Ambulight PDT Multi device to Ambicare Health, detailing the circumstances of the treatment.
3. Consult the pharmaceutical instructions to determine how to proceed in the event of a missed/under treatment.

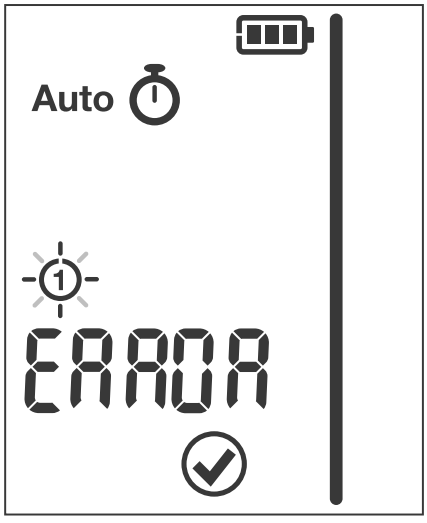
It should be noted that if the Ambulight PDT Multi becomes detached from the treatment area during use, do not allow the light source to shine into the eye.

If the treatment head becomes too hot during treatment

If the light emitting treatment head should overheat, the following screen will be displayed on the controller (**See Screen 12)**

To illustrate that it is an overheating problem, alternate light rays of the treatment head that has overheated will flash.

The digits of the timer will change to read **'ERROR'**.



Screen 12.

If the treatment head has overheated before the treatment cycle is complete then follow the protocol below

1. Note the time at which the treatment head overheated.
2. Return the Ambulight PDT Multi device to Ambicare Health, detailing the circumstances of the treatment.
3. Consult the pharmaceutical instructions to determine how to proceed in the event of a missed/under treatment.

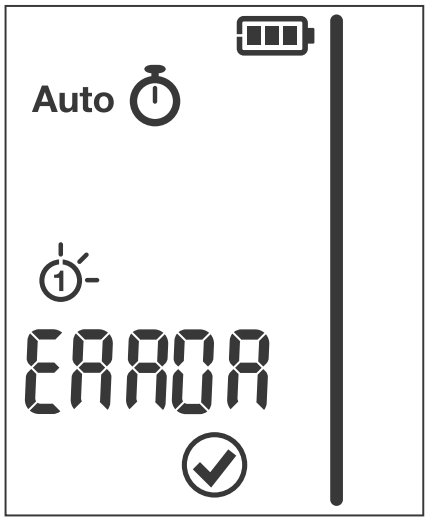
If a light emitting treatment head becomes disconnected from the controller

If a light emitting treatment head becomes disconnected from the controller, the following screen will be displayed. **(See Screen 13)**

The number of light rays that are illuminated on the detached light emitting treatment head refer to the treatment cycle progression time prior to the light emitting treatment head being disconnected.

In the case above, 3 out of the 8 light rays are illuminated on light emitting treatment head 1.

Therefore light emitting treatment head 1 became disconnected 3/8th of the way through the total treatment cycle. The digits of the timer will read **'ERROR'.**



Screen 13.

If the treatment head becomes disconnected from the controller before the treatment cycle is complete then follow the protocol below:

1. Note the time at which the treatment head became detached.
2. Consult the pharmaceutical instructions to determine how to proceed in the event of a missed/under treatment.

Specifications

Product Name: Ambulight PDT Multi
Model Number: PR1002
Operating Wavelength: 640nm +/- 10nm
Operating Temperature/Humidity: 10°C to 40°C / 20% to 85%
Storage & Transport Temperature/Humidity: -5°C to 60°C / less than 85%
Mains Electrical Input: 220V/50Hz/220mA
Mains Charger Electrical Output: 12V/1000mA

Manufactured by:
Ambicare Health Limited
Alba Innovation Centre
Alba Campus
Livingston
EH54 7GA
+44 (0)1506 592 239
www.ambicarehealth.com

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